MEMORANDUM

DATE: August 2, 2002

TO: Division of Shellfish Sanitation Staff

FROM: Robert E. Croonenberghs, Ph.D., Director
Division of Shellfish Sanitation

SUBJECT: Classification - Policy - Contingency Plan for the Control of *Vibrio Parahaemolyticus* in Oysters

Purpose

The purpose of this working memo is to pull together the various NSSP requirements concerning *Vibrio parahaemolyticus* as are found in guidance from the ISSC/NSSP and in the Model Ordinance (MO) of the NSSP.

The first section below contains the Division's contingency plan, which it will follow if certain "triggers" are met. These triggers are either two sporadic cases of *V. parahaemolyticus* illness attributed to oysters (not clams) in the last three years from the same Virginia growing area, or an outbreak. Such sporadic illnesses trigger oyster meat monitoring requirements with the potential to require closure of the area. Outbreaks due to *V. parahaemolyticus* require closure and are already covered under the general outbreak requirements of the MO.

The second section contains the actual guidance from the ISSC/NSSP concerning *V. parahaemolyticus*. You will note that our contingency plan (immediately following) is very similar to part A of the ISSC/NSSP interim guidance (the third section of this working memo). This is by design to make it easy to see that our contingency plan meets the objectives of the guidance. While this guidance is indeed not strictly required by the NSSP, it is offered as its recommendation for a state to follow. As such, the Division is adopting this as its policy.

Contingency Plan

(1) This contingency plan represents the policy of the Virginia Department of Health, Division of Shellfish Sanitation for addressing the control of *Vibrio parahaemolyticus* in oysters. If Virginia waters are confirmed as an original source of oysters associated with two or more confirmed *V. parahaemolyticus* illnesses annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September) or with an outbreak in the last three years, the Department will adopt this document as its *V. parahaemolyticus* contingency plan. Should this contingency plan need to be activated, due either to sporadic illnesses or an outbreak as described above, then oyster meat sampling and the closure of oyster growing areas will be based on the current interim guidance of the National Shellfish Sanitation Program and the most recent edition of the Model Ordinance (MO) found within the Guide for the Control of Molluscan Shellfish.

(2) The administrative procedures and resources necessary to carry out this plan are as follows:

(a) Identification of growing areas affected by *V. parahaemolyticus*

All estuarine and oceanic waters in Virginia that have oysters growing in them can potentially support *V. parahaemolyticus*. Since oyster populations in Virginia occur sporadically, it is impossible to indicate where problems may occur. Given the preference of *V. parahaemolyticus* to grow in mid-salinity waters, one might expect higher concentrations within the Chesapeake Bay than in the marshes of the seaside of the Eastern Shore.

Once water temperatures cool down in the late fall (after November), total counts (*tlh*+) of *V. parahaemolyticus* greatly decrease, and tend not to reoccur until the water warms in April or May. The *tdh*+ counts tend to occur only during the warm portion of this cycle.

(b) Oyster meat sampling and assay program

The Division has been collecting and assaying oysters from 3 different regions of the state since June 1999. Currently, these stations are sampled and assayed year around on a twice a month basis. The areas are the Yeocomico River in the Northern Neck, Swash Hole in the James River, and the Machipongo River on the Eastern Shore.

The only area in the state that has been associated with an illness is the Yeocomico River, which is one of the three areas currently sampled and assayed for V. parahaemolyticus. This area will continue to be sampled in the future.

(c) Closure of oyster growing areas

Shellfish growing areas found to be associated with sporadic *V. parahaemolyticus* illness will be closed according to the interim guidance in the NSSP, whereas any growing area associated with an outbreak of *V. parahaemolyticus* will be closed according to the MO. Should temperature abuse after the harvest of the shellfish be a significant factor, then this will be taken into the consideration for closure.

The Department of Health will close these areas pursuant to Title 28.2, Chapter 8, §§28.2-803 through 28.2-808, §32.1-20, and §9-6.13:4.1, B16 of the *Code of Virginia*.

(d) Prevention of harvest of affected oysters

The Virginia Marine Resources Commission will post these areas as closed with signs and will patrol these areas along with all other closed shellfish areas.

(e) Oyster recall

The Division will use its staff to contact dealers to determine which dealers have shipped oysters from an area that was subsequently closed due to illness. Dealers that have shipped suspect product will be requested to recall the product. The Division has an effective recall capability, due to the cooperation of the shellfish industry, as proven by past recall situations.

(f) Notification of the shellfish industry and the local health jurisdictions

The Division will notify the shellfish industry and the local health departments annually in the early summer, of the potential for illness due to *V. parahaemolyticus*. Furthermore, the Division will make recommendations to the industry for controlling the growth of *V. parahaemolyticus* in shellfish after harvest. In the case of a disease outbreak the shellfish industry, general public and local health departments will be notified of the shellfish growing areas involved, the date of closure and information concerning implicated product that may be in the marketplace.

(g) Health advisory

The Department will issue a general health advisory in the early summer warning the public of the risks of eating raw oysters during the warm weather months.

(h) Time temperature requirements for Virginia harvested shellfish

If two or more cases of Virginia harvested shellfish occur within any 3-year time period for a growing area, then shellstock from that growing area that are intended for raw consumption will be subject to the temperature control requirements of the current version of the MO, Chapter VIII.03. Option 2.

ISSC/NSSP Interim Guidance for the Control of *V. parahaemolyticus*

A. Contingency Plan.

(1) If the waters of a state have been confirmed as an original source of oysters associated with two or more confirmed *V. parahaemolyticus* illnesses annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), or with an outbreak in the last three years, the Authority should develop and adopt a *V. parahaemolyticus* contingency plan.

(2) The plan should define the administrative procedures and resources necessary to accomplish the following:

(a) Identify and define growing areas in the state affected by *V. parahaemolyticus* based on hydrographic and geological parameters and other considerations relevant to control of a naturally occurring pathogen;

(b) Conduct an oyster meat sampling and assay program in those areas which have been associated with a *V. parahaemolyticus* illness;

(c) Close affected oyster growing areas;

(d) Prevent harvesting of affected oysters;

(e) Provide for oyster recall if an oyster growing area is closed as a result of illness;

(f) Notify the shellfish industry and the local health jurisdictions in the state of the potential for illnesses due to *V. parahaemolyticus* prior to historical times of onset or at a minimum of once a year;

(g) Issue a health advisory to the public about the potential problem and advise the industry to educate wholesalers, retailers, and consumers about the potential problem, with recommendations that oysters not be consumed raw during periods historically affected by *V. parahaemolyticus*.

(3) The plan may include agreements or memoranda of understanding between the Authority and individual oyster harvesters and processors to allow harvesting of oysters from growing areas which have been placed in the closed status, as specified in C. for:

(a) Post-harvest treatment by a process which has been demonstrated to reduce *V. parahaemolyticus* levels in oysters to non-detectable; or,
(b) Shucking and labeling “for cooking only”; or,
(c) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be sold to a retailer or food establishment, food processor, or to a shucker-packer and labeled in accordance with (3)(b); or,
(d) Under specific circumstances, as approved by the Authority, where the oyster shellstock will be cooked and controls exist to ensure cooking.

B. *Vibrio parahaemolyticus* Monitoring

(1) In all areas where two or more confirmed *V. parahaemolyticus* illnesses have occurred annually in the most recent three years (excluding years when growing areas were closed at least half of the period from June through September), representative samples of oysters should be collected at least monthly during harvest periods historically associated with illnesses and otherwise as determined by the Authority. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus.* *

(2) In all areas where a confirmed *V. parahaemolyticus* outbreak has occurred within the last three years, representative samples of oysters should be collected when environmental conditions are favorable for V. parahaemolyticus growth and/or periods historically associated with illness as determined by the Authority Samples should be collected and analyzed weekly during the year of and the first year after an outbreak, and at least monthly during the second and third years after an outbreak. All samples will be analyzed using the direct plating procedures and gene probe methods or enrichment PCR procedures for total (*tlh*+ colonies) and pathogenic (*tdh*+ colonies) *V. parahaemolyticus.*

(3) In order to determine the number of samples that would be appropriate for *V. parahaemolyticus* monitoring, the following factors should be considered:

(a) The size of the growing area;
(b) The amount of oyster shellstock typically harvested from the area;
(c) The sensitivity of the methodology.

(4) In the event that emerging technologies and research identify pathogenic strains other than or in addition to *tdh*+ strains, the Authority may adopt and FDA may approve other or additional monitoring and control methods for preventing *V. parahaemolyticus* illnesses.

C. Closed Status of Growing Area Based On Monitoring Results.

(1) The growing area as defined in accordance with A.(2)(a) should be placed in the closed status for oyster harvest, except as allowed under A.(3), if a total of 5 or more pathogenic (*tdh*+) *V. parahaemolyticus* colony-forming units (CFU) per 0.1 gram, confirmed by at least one pathogenic (*tdh*+) *V. parahaemolyticus* CFU per 0.1 gram by replicate analysis, are found for any oyster sample from the harvest area.** If any sample shows total (*tlh*+) *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic *V. parahaemolyticus*. Should any of these additional samples show 5 or more pathogenic *V. parahaemolyticus* CFU per 0.1 gram, confirmed by at least one pathogenic *V. parahaemolyticus* by replicate analysis, the area will be placed in the closed status for oyster harvest, except as allowed under A.(3).

(2) The closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis. If any sample shows total *V. parahaemolyticus* counts above 5,000 CFU per gram, then additional samples (twice the number collected as determined by the Authority) should immediately be collected and analyzed for pathogenic (*tdh*+) and total (*tlh*+) *V. parahaemolyticus*. Should those samples show fewer than 5 pathogenic (*tdh*+) *V. parahaemolyticus* CFU in 0.1 gram, or show no pathogenic *V. parahaemolyticus* by replicate analysis, the growing area should be opened.

(3) The analysis leading to a decision to return a growing area to the open status should be adequately documented.

D. Illness Outbreak.

(1) When a growing area is implicated in a *V. parahaemolyticus* illness outbreak, the Authority shall follow the procedures prescribed in Chapter II Section@.01A through E. If a growing area is closed due to an illness outbreak, the closed status should remain in effect until two consecutive representative samples of oyster meats, collected a minimum of four days apart, show no pathogenic (*tdh*+) *V. parahaemolyticus* CFU in replicate 0.1 gram portions of oyster meat and less than 5,000 total (*tlh*+) *V. parahaemolyticus* CFU per gram.

(2) If additional confirmed *V. parahaemolyticus* illnesses occur within 2 weeks of re-opening, they should be considered a continuation of the illness outbreak. The growing area should immediately be placed in the closed status, and re-opening may only occur when environmental conditions shift to those unfavorable to the growth of *V. parahaemolyticus*, or the Authority, in conjunction with the state epidemiologist, develops and implements a sampling plan.

E. Records.

The Authority should maintain a copy of all of the following records:

(1) All information, including monitoring data, relating to the levels of *V. parahaemolyticus* in the oyster growing areas;

(2) Copies of notices placing growing areas in the closed status;

(3) Evaluation reports; and,

(4) Copies of notices returning growing areas to the open status.

* Direct plating procedure by Cook, D.W. et al, 1999

** A replicate is defined as 2 filters for tdh analysis from the same homogenate at the same dilution.